

K870952 THEOPHYLLINE FPIA REAGENT SETMar 31, 1987
21 days to decisionK870952 · Product code: **KLS** · Toxicology
Source: <https://www.510kdatabase.net/k870952/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Mar 10, 1987
Decision date	Mar 31, 1987
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	DENNIS MURRAY
510(k) history	164 submissions · 164 cleared · 1984-2002

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